K111200

OCT 12 2011

1/5

GE Healthcare
510(k) Premarket Notification Submission

510(k) Summary

In accordance with 21 CFR 807.92 the following summary of information is provided:

Date: April 27, 2011

Submitter: GE Healthcare,

(GE Medical Systems Information Technologies, Inc.)
8200 West Tower Avenue
Milwaukee, WI 53223

Primary Contact Person: Ms. Carol Alloian
Regulatory Leader

GE Healthcare,
(GE Medical Systems Information Technologies, Inc.)
Telephone: 224 280-1008
Fax: 847 589 8524

Secondary Contact Person: Mr. Philip Malca
Regulatory Affairs Director

GE Healthcare,
(GE Medical Systems Information Technologies, Inc.)
Telephone: 33(0) 1 3070 4207
Fax: 33(0) 1 3070 4399

Device: Trade Name: Mac-Lab, CardioLab, ComboLab, and SpecialsLab Recording Systems

Common/Usual Name: Hemodynamic and Electrophysiology (EP) Recording Systems

Classification Names: 21 CFR 870.1425 Computer, Diagnostic Programmable

Product Code: DQK

Predicate Device(s): K061741 Mac-Lab, CardioLab, ComboLab, and SpecialsLab System

Device Description: Mac-Lab, CardioLab, ComboLab, and SpecialsLab Recording Systems are hemodynamic and electrophysiology (EP) recording systems.

The product will be available in the following configurations: Mac-Lab application, CardioLab application, SpecialsLab application, or a combination of both CardioLab and Mac-Lab applications marketed as ComboLab. The product designated as SpecialsLab is the same as the Mac-Lab System with the exception that it will support fewer options. The SpecialsLab System performs the same intended use as the Mac-Lab, executes the same software, and runs on the same hardware.

The Mac-Lab, CardioLab, and ComboLab Recording Systems are each available in several configurations ranging from basic to full advanced functionality.

Intended Use/ Indications for Use:

Mac-Lab

The Mac-Lab System is intended for acquiring, filtering, digitizing, amplifying, measuring and calculating, displaying, recording and monitoring of clinical data from adult and pediatric patients. The Mac-Lab System is configurable. Clinical data includes: ECG waveforms, heart rate, pulse oximetry (SpO2), respiration rate, CO2 (EtCO2), temperature, hemodynamic measures [e.g. valve gradients and areas, cardiac output, shunts, Fractional Flow Reserve (FFR), invasive and noninvasive blood pressure] Physiological parameters such as diastolic, systolic, and mean pressures, and heart rate are derived from the signal data, displayed and recorded. The data is entered manually or acquired via interfaced devices and/or information systems and may be used for report generation.

Procedural information and optional anatomical and physiological imaging and data devices may be interfaced (e.g. X-ray, ultrasound, patient monitors and information systems). The Mac-Lab System can display, store and annotate images previously acquired and stored by other systems. Data may be provided to other systems via multiple formats (e.g. HL7, DICOM, Analog outputs). Data may be received from other devices via multiple formats (e.g. DICOM, Analog inputs).

Optional accessories for hardware and software include research

Intended Use/ Indications for Use:

tools to be used exclusively outside active patient care settings. The purpose of the research tools is to assist researchers or clinicians in developing algorithms.

The Mac-Lab System does not have alarms, does not generate energy delivered to the patient, does not administer drugs and does not perform any life-supporting or life-sustaining functions. The Mac-Lab System is not intended for use on unattended patients, or in situations where diagnostic arrhythmia detection is required.

The Mac-Lab System provides the ability to transmit patient data for storage, analysis and viewing at distributed locations within a clinical facility via network connectivity. The Mac-Lab System also functions as a stand-alone device. The Mac-Lab System is used in a variety of hospital and clinical settings including interventional laboratories (e.g. cardiac catheterization and radiology), operating room environments, and pre and post areas all under the direct supervision of licensed healthcare practitioners who are responsible for interpreting the data.

CardioLab
The CardioLab System is intended for acquiring, filtering, digitizing, amplifying, measuring and calculating, displaying, recording and monitoring of clinical data from adult and pediatric patients. The CardioLab System is configurable. Clinical data includes: ECG waveforms, intracardiac signals, stimulus data, ablation data, pulse oximetry (SpO2), respiration rate, CO2 (EtCO2), temperature, and invasive and noninvasive blood pressure. Physiological parameters such as diastolic, systolic, mean pressures, heart rate, and cycle length are derived from the signal data, displayed and recorded. The data is entered manually or acquired via interfaced devices and/or information systems and may be used for report generation.

Procedural information and optional anatomical and physiological imaging and data devices may be interfaced [e.g. X-ray, ultrasound, mapping systems, ablation generators (e.g. RF and cryogenic)], stimulators, patient monitors and information systems. The CardioLab System can display, store and annotate images previously acquired and stored by other systems. Data may be provided to other systems via multiple formats (e.g. HL7,

Intended Use/ Indications for Use:

DICOM, Analog outputs). Data may be received from other devices via multiple formats (e.g. DICOM, Analog inputs).

Optional accessories for hardware and software include research tools to be used exclusively outside active patient care settings. The purpose of the research tools is to assist researchers or clinicians in developing algorithms.

Optional accessories for hardware and software includes a waveform simulator to be used exclusively outside active patient care settings. The waveform simulator may be used for training, demonstration without a patient attached, and as a troubleshooting tool on the CardioLab System.

The CardioLab System does not have alarms, does not generate energy delivered to the patient, does not administer drugs and does not perform any life-supporting or life-sustaining functions. The CardioLab System is not intended for use on unattended patients, or in situations where diagnostic arrhythmia detection is required.

The CardioLab System provides the ability to transmit patient data for storage, analysis and viewing at distributed locations within a clinical facility via network connectivity. The CardioLab System also functions as a stand-alone device. The CardioLab System is used in a variety of hospital and clinical settings including interventional laboratories (e.g. electrophysiology and cardiac catheterization), operating room environments, and pre and post areas all under the direct supervision of licensed healthcare practitioners who are responsible for interpreting the data.

SpecialsLab
The SpecialsLab System executes the same software and runs on the same hardware in the same environments as the Mac-Lab System. Products designated as a SpecialsLab System support fewer options than the Mac-Lab system.

ComboLab
The ComboLab System is the combination of both the Mac-Lab and CardioLab Systems. The ComboLab System allows the user to run either the Mac-Lab System or the CardioLab System,

although only one system may be used at a time. The ComboLab System executes the same software and runs on the same hardware in the same environments as the Mac-Lab and CardioLab Systems.

Technology: The proposed Mac-Lab, CardioLab, ComboLab, and SpecialsLab Recording Systems employ the same fundamental scientific technology as their predicate devices.

Determination of Substantial Equivalence:

Summary of Non-Clinical Tests:

The Mac-Lab, CardioLab, ComboLab, and SpecialsLab Recording Systems and their applications comply with voluntary standards as detailed in Section 9, 11 and 17 of this premarket submission. The following quality assurance measures were applied to the development of the system:

- Risk Analysis
- Requirements Reviews
- Design Reviews
- Testing on unit level (Module verification)
- Integration testing (System verification)
- Performance testing (Verification)
- Safety testing (Verification)
- Simulated use and Usability testing (Validation)

Summary of Clinical Tests:

The subject of this premarket submission, Mac-Lab, CardioLab, ComboLab, and SpecialsLab Recording Systems, did not require clinical studies to support substantial equivalence.

Conclusion: GE Healthcare considers the Mac-Lab, CardioLab, ComboLab, and SpecialsLab Recording Systems to be as safe and effective as, and to have performance substantially equivalent to, the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

OCT 12 2011

GE Healthcare
c/o Ms. Carol Alloian, RAC
Regulatory Leader, Interventional Systems
9900 W Innovation Drive
Wauwatosa, WI 53266-4856

Re: K111200
Trade/Device Names: Mac-Lab, CardioLab, ComboLab and SpecialsLab Recording Systems, Version 6.9
Regulatory Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: Class II (Two)
Product Code: DQK
Dated: September 19, 2011
Received: September 21, 2011

Dear Ms. Alloian:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K111200

GE Healthcare
510(k) Premarket Notification Submission

510(k) Number (if known): To Be Assigned K111200

Device Name: Mac-Lab, CardioLab, ComboLab, and SpecialsLab Recording Systems

Indications for Use: **Mac-Lab**

The Mac-Lab System is intended for acquiring, filtering, digitizing, amplifying, measuring and calculating, displaying, recording and monitoring of clinical data from adult and pediatric patients. The Mac-Lab System is configurable. Clinical data includes: ECG waveforms, heart rate, pulse oximetry (SpO2), respiration rate, CO2 (EtCO2), temperature, hemodynamic measures [e.g. valve gradients and areas, cardiac output, shunts, Fractional Flow Reserve (FFR), invasive and noninvasive blood pressure] Physiological parameters such as diastolic, systolic, mean pressures, and heart rate are derived from the signal data, displayed and recorded. The data is entered manually or acquired via interfaced devices and/or information systems and may be used for report generation.

Procedural information and optional anatomical and physiological imaging and data devices may be interfaced (e.g. X-ray, ultrasound, patient monitors and information systems). The Mac-Lab System can display, store and annotate images previously acquired and stored by other systems. Data may be provided to other systems via multiple formats (e.g. HL7, DICOM, Analog outputs). Data may be received from other devices via multiple formats (e.g. DICOM, Analog inputs).

Optional accessories for hardware and software include research tools to be used exclusively outside active patient care settings. The purpose of the research tools is to assist researchers or clinicians in developing algorithms.

The Mac-Lab System does not have alarms, does not generate energy delivered to the patient, does not administer drugs and does not perform any life-supporting or life-sustaining functions. The Mac-Lab System is not intended for use on unattended patients, or in situations where diagnostic arrhythmia detection is required.

The Mac-Lab System provides the ability to transmit patient data for storage, analysis and viewing at distributed locations within a clinical facility via network connectivity. The Mac-Lab System also functions as a stand-alone device. The Mac-Lab System is used in a variety of hospital and clinical settings including interventional laboratories (e.g. cardiac catheterization and radiology), operating room environments, and pre and post areas all under the direct supervision of licensed healthcare practitioners who are responsible for interpreting the data.

Prescription Use_X___ AND/OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K111200

GE Healthcare
510(k) Premarket Notification Submission

510(k) Number (if known): To Be Assigned K111200

Device Name: Mac-Lab, CardioLab, ComboLab, and SpecialsLab Recording Systems

Indications for Use: **CardioLab**

The CardioLab System is intended for acquiring, filtering, digitizing, amplifying, measuring and calculating, displaying, recording and monitoring of clinical data from adult and pediatric patients. The CardioLab System is configurable. Clinical data includes: ECG waveforms, intracardiac signals, stimulus data, ablation data, pulse oximetry (SpO2), respiration rate, CO2 (EtCO2), temperature, and invasive and noninvasive blood pressure. Physiological parameters such as diastolic, systolic, mean pressures, heart rate, and cycle length are derived from the signal data, displayed and recorded. The data is entered manually or acquired via interfaced devices and/or information systems and may be used for report generation.

Procedural information and optional anatomical and physiological imaging and data devices may be interfaced [e.g. X-ray, ultrasound, mapping systems, ablation generators (e.g. RF and cryogenic)], stimulators, patient monitors and information systems. The CardioLab System can display, store and annotate images previously acquired and stored by other systems. Data may be provided to other systems via multiple formats (e.g. HL7, DICOM, Analog outputs). Data may be received from other devices via multiple formats (e.g. DICOM, Analog inputs).

Optional accessories for hardware and software include research tools to be used exclusively outside active patient care settings. The purpose of the research tools is to assist researchers or clinicians in developing algorithms.

Optional accessories for hardware and software include a waveform simulator to be used exclusively outside active patient care settings. The waveform simulator may be used for training, demonstration without a patient attached, and as a troubleshooting tool on the CardioLab System.

The CardioLab System does not have alarms, does not generate energy delivered to the patient, does not administer drugs and does not perform any life-supporting or life-sustaining functions. The CardioLab System is not intended for use on unattended patients, or in situations where diagnostic arrhythmia detection is required.

The CardioLab System provides the ability to transmit patient data for storage, analysis and viewing at distributed locations within a clinical facility via network connectivity. The CardioLab System also functions as a stand-alone device. The CardioLab System is used in a variety of hospital and clinical settings including interventional laboratories (e.g. electrophysiology and cardiac catheterization), operating room environments, and pre and post areas all under the direct supervision of licensed healthcare practitioners who are responsible for interpreting the data.

Prescription Use_X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use_ _ (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K111200

GE Healthcare
510(k) Premarket Notification Submission

510(k) Number (if known): To Be Assigned K111200

Device Name: Mac-Lab, CardioLab, ComboLab, and SpecialsLab Recording Systems

Indications for Use:

SpecialsLab
The SpecialsLab System executes the same software and runs on the same hardware in the same environments as the Mac-Lab System. Products designated as a SpecialsLab System support fewer options than the Mac-Lab system.

ComboLab
The ComboLab System is the combination of both the Mac-Lab and CardioLab Systems. The ComboLab System allows the user to run either the Mac-Lab System or the CardioLab System, although only one system may be used at a time. The ComboLab System executes the same software and runs on the same hardware in the same environments as the Mac-Lab and CardioLab Systems.

Prescription Use_x___ AND/OR Over-The-Counter Use_
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K111200